

## **I. REMARKS**

Claims 1, 2, 7, 10, 20 and 21 are pending.

### **Obviousness**

The Action alleges that the claims 1-2, 7 and 10 are unpatentable over WO 98/29375 ("Atlas") in view of US 6,303,139 ("Passi") and in further view of Delack et al. (US 2003/0113309 A1). Applicant respectfully traverses the rejection.

The Action alleges that Atlas teaches using compound J to treat oxidative stress; that Passi teaches oxidative stress is significantly involved in MS; and that Delack further teaches that MS patients have an anti-oxidant deficiency. Therefore, the Action concludes that it would have obvious to treat a subject suffering from MS with compound J.

In response to these allegations, Applicants respectfully submit the attached declaration of Daphne Atlas, a named inventor of the subject application. Dr. Atlas is a professor of chemistry. One of her specialties for the last 15 years is antioxidant chemical compounds, especially in the area of central nervous system diseases, such as MS. Decl., para. 2.

### **I. The proven success of other compounds in treating MS**

#### **A. Salen-metal complex compounds**

Among its allegation, the current Office Action states that Malfroy-Camine et al. (US Pat. No. 6,589,948; hereinafter "Malfroy") provides examples of other antioxidant compounds that are indicated for treating MS. Specifically, column 4, lines 26-46 of Malfroy cites the class of antioxidant salen-metal complex compounds for treating MS, as well as many other CNS diseases.

However, Malfroy provides no data whatsoever that shows that any species of this class of compounds can treat any CNS disease, much less MS. Moreover, it has been almost ten years since Malfroy was filed, and over seven years since this patent issued. Professor Atlas is not aware of any publication that provides any data that shows that any species of this class of compounds can treat MS. Decl., para. 4.

### **B. Vitamins C and E**

Previously, Applicants cited an article showing that, while vitamins C and E were thought to help prevent the onset of MS, the data proved otherwise. In response, the current Action suggests that while these vitamins may not prevent MS, they could possibly treat MS.

However, there is absolutely no data showing that either of these vitamins can treat MS. Indeed, while it was originally speculated that these vitamins may help in preventing MS, Professor Atlas is not aware of any such speculation as to either of these vitamins thought to treat MS. Decl., para. 6.

Applicants previously cited this article merely to show that, when it comes to antioxidant drug candidates for CNS diseases, especially MS, the skilled artisan would be very skeptical. Such skepticism would apply whether a given drug candidate was thought to treat or prevent MS. Decl., para. 7.

### **II. The level of involvement of oxidative stress**

The Office Action also alleges that because oxidative stress is significantly involved in the pathogenesis of MS, it would be obvious to treat MS with an antioxidant compound such as compound J.

Applicants do not take issue with the fact that oxidative stress may be a significant contributor towards the onset or progression of MS. But despite the significant role oxidative stress might play, the track record of antioxidants to successfully treat MS has been scanty at best. And, as discussed above, the

disclosure of Malfroy regarding salen-metal complex compounds for treating MS amounts to nothing more than baseless speculation. Given this track record, regardless of whether oxidative stress plays a significant role in the pathogenesis of MS, at the time of the subject invention it would not have been obvious that compound J, or any other antioxidant drug candidate, would successfully treat MS. Decl., para. 9.

### **III. Regarding the table provided**

Previously, Applicants provided a table of known drugs that treat MS. The point of the table was to show that out of all the known drugs for treating MS, only one drug is an antioxidant, although many, many antioxidant drugs are known. This clearly shows to Dr. Atlas that a given antioxidant, such as compound J, is not obvious that it can treat MS unless and until actual results are shown. Decl., para. 10.

The Action further alleges that there is no reason to believe this list is comprehensive or that it represents all the treatments known in the art, but rather may be limited to only those which have already been approved by the FDA. To the best of Professor Atlas' knowledge, this is a comprehensive list. In other words, as of the date of the subject invention and even today, she is not aware of any other antioxidant compounds that have been shown to successfully treat MS. Decl., para. 11.

### **IV. Regarding other CNS diseases**

The Office Action argues that the role oxidative stress may play in other CNS diseases is not relevant regarding whether it would be obvious to treat MS with a particular antioxidant, such as compound J.

Applicants respectfully disagree with this allegation. The fact that oxidative stress may play a significant role in the pathogenesis of MS is not unique to MS. Indeed, oxidative stress may play a significant role in several other CNS diseases, such as Alzheimer's and Parkinson's disease. And like MS,

the track record of successfully treating these diseases with antioxidants has been scanty if not poor. This poor track record for CNS diseases in general further supports the non-obviousness of the subject invention, which is directed to treating MS in particular. Decl., para. 13.

For all these reasons, Applicants respectfully request that this rejection be withdrawn.

**II. CONCLUSION**

In view of the above amendments and remarks it is respectfully submitted that the claims are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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**Enclosures:**

- Petition for Extension (Two Months)
- Request for Continued Examination (RCE)
- Executed Declaration by Inventor Atlas